

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,206	02/01/2002	James F. Castner	PH-7123	9887
23914	7590	07/29/2004	EXAMINER	
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			LEE, BENJAMIN C	
			ART UNIT	PAPER NUMBER
			2632	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/062,206	CASTNER ET AL.	
	Examiner	Art Unit	
	Benjamin C. Lee	2632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/9/02, 1/3/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 51-52 objected to because of the following informalities: In claims 51 & 52, line 1, "claims" should have read --claim--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 15-16 and 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 15 appears should have depended on claim 14 since a claim could not depend on itself.

2) Claim 16 appears should have depended on claim 15 since a claim could not depend on itself.

3) Claims 47-48 appear should have depended on claims 40 and 47, respectively, since claims 15-16 which depended on claim 14 already included the claimed limitation of claims 47-48.

4) Claims 49-50 appear should have depended on claims 40 and 49, respectively; also, "analyte" of line 1 of the claims should have read --sample-- since the independent claim already established the antecedence that the "analyte" is a gas and therefore could not be at the same time a "liquid".

(Note: The following prior art consideration will treat the claim dependencies as what they appear should logically have been.)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plester et al. (US pat. #5,067,616) in view of Bachur, Jr. et al. (US pub. #2003/0111607, with effective filing date of Provisional application #60/236,164 on Sept. 29, 2000).

1) In considering claim 1:

Plester et al. discloses an apparatus (Figs. 2 & 4) for monitoring the presence of an analyte in a vial (bottle) comprising: a vial feeding mechanism (inherent in Figs. 2-4 for feeding vials onto conveyor system 23, 31, 43); a conveyor (23, 31, 43) operatively associated with the vial feeding mechanism for receiving vials from the vial feeding mechanism; an analyzer (15, 45) operatively associated with the conveyor for determining a value of a spectral property of a sample in the vial, the spectral property being dependent on analyte concentration (col. 13, lines 19-25; col. 9, lines 34-42 and col. 10, lines 31-38); and a mechanism for determining and generating signals indicative of vials wherein the presence of the analyte is detected as product vials and for determining and generating signals indicative of vials wherein the absence of the analyte is detected as rejected vials (col. 9, lines 42-45 and col. 10, lines 38-47); whereby the analyzer can be in the form of "headspace vapor analysis" that determines a value of a spectral property at a position within the headspace of the vials according to col. 18, lines 1-5, in which case the vials under analysis would inherently be closed to retain the headspace vapor);

While Bachur, Jr. et al. discloses a system apparatus for monitoring the presence of an analyte in a closed vial comprising an analyzer (152) for determining a value of a spectral property at a position within headspaces of the vials, the spectral property being dependent on analyte concentration (Figs. 4-13 and Abstract, whereby Figs. 8-9 show analyte presence and concentration detection based on detected IR intensity as well as spectral absorption peak); and known use of an indicator operatively associated with the analyzer for indicating the analyzed results in such a system (page 1, right column, lines 12-15).

In view of the teachings Plester et al. and Bachur, Jr. et al., it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to include an indicator showing the results of the analyzer such as taught by Bachur, Jr. et al. in an analyte presence monitoring system such as taught by Plester et al. so that an operator may be made aware of the monitored outcome to assess compliance of the rejection mechanism, e.g. to detect faults.

2) In considering claim 2, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 1, wherein:

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention that the feeding function in a system such as taught by Plester et al. and Bachur, Jr. et al. can be implemented in a 2-steps procedure using a transporter between the vial feeding mechanism and the conveyor for transferring vials thereto without unexpected results.

3) In considering claim 3, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 2, wherein:

Since Plester et al. teaches detecting and separating rejected contaminated containers and accepted uncontaminated containers, it would have been obvious to one of ordinary skill in

Art Unit: 2632

the art at the time of the claimed invention to include a first vial counter operatively associated with the transporter for counting the number of vials received by the transporter in a system such as taught by Plester et al. and Bachur, Jr. et al. for use in well-known accounting practices such as inventory control and tracking the percentage of acceptable and rejected containers using additional counters at the rejection station, etc.

4) In considering claim 4, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 1, including:

--the claimed comprising a transferrer for receiving vials from the conveyor (transferring mechanisms for transferring vials between the detection station conveyor to the rejection conveyor 43 inherent in Figs. 2 and 4 of Plester et al.)

5) In considering claim 5, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 4, including:

--the claimed comprising a reject station (21, 49 of Plester et al.) operatively associated with the transferrer for receiving rejected vials from the transferrer.

6) In considering claim 6, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 4, plus the consideration of claim 3, wherein:

--the claimed comprising a second vial counter operatively associated with the transferrer for counting the number of vials received by the transferrer is met by said additional counters for the purposes of determining percentage of rejection, for example.

7) In considering claims 7-9, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 4, wherein:

Art Unit: 2632

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention that in order to implement well-known quality control of the contamination detection and rejection system such as taught by Plester et al. and Bachur, Jr. et al., a sampler operatively associated with the transferrer for removing sample collection vials from the transferrer, and a sample collection station operatively associated with the sampler for receiving the sample collection vials from the sampler can be used to sample the rejected vials for testing to ensure those vials should indeed be rejected, and a third vial counter operatively associated with the sampler for counting the number of vials received by the sampler can be used to track percentile errors to determine acceptable or unacceptable error rates to determine need for recalibration of the system.

8) In considering claim 10, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 4, wherein:

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention that a labeler can be including in a system such as taught by Plester et al. and Bachur, Jr. et al. to be operatively associated with the transferrer for labeling product vials (accepted, non-rejected), received from the transferrer as a way to mark and differentiate them from rejected vials in order to prevent confusion between the accepted versus rejected vials.

9) In considering claims 11-12, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 1, wherein:

While Plester et al. indicated that the analyte can be in the form of various expected product ingredient or byproduct gases including hydrocarbons (col. 18, line 4 of Plester et al.) and carbene dioxide (Abstract of Bachur, Jr. et al.), it would have been obvious to one of

Art Unit: 2632

ordinary skill in the art at the time of the claimed invention that depending on the product ingredients in the vials, the residue analyte can include various substances and gases, such that monitoring an analyte including perfluorocarbon gas comprising perfluoropropane constitutes an intended use of a system such as taught by Plester et al. and Bachur for monitoring such vials having such particular gases.

10) In considering claim 13, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 1, wherein:

Plester et al. shows separating the vials on the conveyor by predetermined spacing in the monitoring system (Figs. 2 & 4) that inherently helps in preventing the signal from the analyzer from saturating the indicator as the vials are moved through the optical path of the analyzer. It would have been obvious to one of ordinary skill in the art at the time of the claimed invention that if a particular conveying arrangement/environment is employed or implemented such that such spacing is reduced when using a system such as taught by Plester et al. And Bachur, Jr. et al., a separator can be used between the vials on the conveyor to ensure prevention of such saturation.

11) In considering claim 14, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in the considerations of claims 1, 7 & 10, including:

--the claimed comparing the measured value of the spectral property with a predetermined limit criteria to determine the presence of the analyte (17 of Plester et al.)

12) In considering claims 15-16, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 14, plus the considerations of claims 11-12.

Art Unit: 2632

13) In considering claim 17, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in the considerations of claim 1, including:

- a) claimed identifying the absorption peak and intensity (Figs. 8-9 of Bachur, Jr. et al.);
- b) claimed performing first and second spectral analysis of gas contained within a headspaces of a test vial and a sample vial, respectively, for comparison (col. 4, lines 8-45 of {Plester et al.})

14) In considering claim 18, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 17, including:

- the claimed wherein the spectral region identified is an infrared spectral region (col. 13, line 19 of Plester et al. and Figs. 8-9 of Bachur, Jr. et al.)

15) In considering claims 19-20, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 17, including:

- the claimed wherein the first and second intensities are determined from a height or area of the absorption peak (Figs. 8-9 of Bachur, Jr. et al.)

16) In considering claim 21, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 20, wherein:

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention that either a partial least squares algorithm or a peak height algorithm can be used to determine the area of the absorption peak in a system such as taught by Plester et al. and Bachur, Jr. et al. without unexpected results.

17) In considering claims 22-23, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 17, plus the consideration of claims 11-12.

Art Unit: 2632

18) In considering claim 24, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in the consideration of claim 1, wherein:

--the claimed quantitative monitoring is met by the concentration monitoring of Plester et al. and Bachur, Jr. et al, and the claimed indicating vials wherein the quantity of analyte measured is different than the analyte in the product vials and detected as rejected vials is met by Abstract of Plester et al.

19) In considering claims 25-36, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 24, plus the consideration of claims 2-13, respectively.

20) In considering claim 37, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in the consideration of claims 14 & 24.

21) In considering claims 38-39, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 37, plus the consideration of claims 15-16, respectively.

22) In considering claim 40, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in the consideration of claims 17 & 24.

23) In considering claims 41-46, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 40, plus the consideration of claims 18-23, respectively.

24) In considering claims 47-48, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 40, plus the consideration of claims 15-16, respectively.

25) In considering claims 49-50, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 40, plus the consideration of claim 47, wherein:

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention that the presence of perfluorocarbon gas in the closed headspace of the vial is due to

Art Unit: 2632

the presence of a sample such as a fluorinated liquid that comprises liquid perfluorocarbon in a system such as taught by Plester et al. and Bachur, Jr. et al. as an intended use of the vial rejection process for a particularly intended type of vials having particular residues.

26) In considering claim 51, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 49, wherein:

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention that the presence of perfluorocarbon gas in the closed headspace of the vial is due to the presence of a sample such as a fluorinated liquid in one or more of the claimed perfluoroliquids in a system such as taught by Plester et al. and Bachur, Jr. et al. as an intended use of the vial rejection process for a particularly intended type of vials having particular residues.

27) In considering claim 52, Plester et al. and Bachur, Jr. et al. made obvious all of the claimed subject matter as in claim 14, wherein:

Since the infrared spectral analysis in the Plester et al. and Bachur, Jr. et al. system is done from externally of the sample vials, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention that such vials would either be made of a glass material or a plastic material "capable of affording" a spectral window through which specific analytes may be detected, i.e. a portion or the whole of the plastic vial is "capable" of allowing analyte detection externally.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1) US patents 5614718, 4971900, 6395538 and EU patent pub. EP0306307A2

Art Unit: 2632

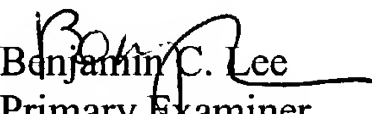
--Similar container headspace analyte analysis/monitoring systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin C. Lee whose telephone number is (703) 306-4223.

The examiner can normally be reached on Mon -Fri 11:00Am-7:30Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Wu can be reached on (703) 308-6730. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Benjamin C. Lee
Primary Examiner
Art Unit 2632

B.L.